September 14, 2000

Hon. Saxby Chambliss
U.S. House of Representatives
1019 Longworth HOB
Washington, DC 20515

Re: HCFA's compliance with the Regulatory Flexibility Act in promulgating the interim final rule on hospital conditions of participation and the use of patient restraints. 64 Fed. Reg.36,070 (July 2, 1999)

Dear Congressman Chambliss:

Pursuant to your request dated September 11, 2000, the Chief Counsel presents the following opinion in regard to 1) HCFA's compliance with the RFA in the above-referenced rulemaking, and 2) the rule's impact on small rural hospitals.

The Office of Advocacy of the U.S. Small Business Administration (SBA) was established by Congress pursuant to Pub. L. No. 94-305 to represent the views of small business before federal agencies and Congress. One of the primary functions of the office is to measure the costs and other effects of government regulation on small businesses and make proposals for eliminating excessive or unnecessary regulations of small businesses. The Chief Counsel of Advocacy is required by section 612(a) of the Regulatory Flexibility Act (RFA)[1] to monitor agency compliance with the RFA and to report annually to Congress and the President on such compliance. The Chief Counsel of Advocacy is also authorized to appear as *amicus curiae* in any action brought in court to review a rule. In any such action, the Chief Counsel is authorized to present views with respect to compliance with the RFA, the adequacy of the rulemaking record with respect to small entities, and the effect of the rule on small entities.[2]

**Background**

The interim final rule, which became effective on August 2, 1999, introduces a new patients' rights condition of participation (CoP) that hospitals[3] must meet to be approved for, or to continue participation in, the Medicare and Medicaid programs. The rule presents six standards to ensure minimum protections of each patient's physical and emotional health and safety. At least two of the new standards deal with a patient's rights to enjoy freedom from restraints unless deemed clinically necessary by a physician.

[1] 5 U.S.C. § 601 et seq. as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. No. 104-121, 110 Stat. 857.
[2] *Id.* at § 612
[3] The patients' rights CoP applies to all Medicare- and Medicaid-participating hospitals (i.e., short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug hospital facilities).

Specifically, the rule requires that a physician or licensed independent practitioner see the patient face-to-face within one hour of the application of the restraint or the use of seclusion in situations where a restraint must be used for behavior management (as opposed to situations where restraint must be used during acute medical or surgical services). It is very important, in situations where restraint is being used for behavior management, that patients remain restrained only as long as clinically necessary to prevent unnecessary injury to the patient and to preserve the patient's rights.

The rule also sets limits for each written order for physical restraints or seclusion based on a patient's age—a maximum of 4 hours for adults, 2 hours for adolescents and 1 hour for children 9 and under. The orders are renewable at the designated maximum intervals for a period up to 24 hours. After 24 hours a physician or licensed practitioner must see and assess the patient again before issuing a new order. In other words, the rule prohibits the use of standing orders or "as needed" (i.e., PRN) orders. Obviously, this provision is intended to prevent patients from being restrained or secluded longer than necessary.

These prescriptive provisions were not contained in the proposed rule of December 19, 1997. In fact, the proposed rule did not have separate provisions for behavioral uses versus medical or surgical uses of restraints. The original proposal contemplated using a more general and less prescriptive approach: "our expectation is that a hospital would impose restraints or seclusion only when absolutely necessary to prevent immediate injury to the patient or others and when no alternative means are sufficient to accomplish this purpose. We also expect that when restraints or seclusion are used, the plan of care should address how and when such practices are to be employed, and patients placed under restraints or in seclusion would be released as soon as they no longer pose an immediate threat of injury to themselves or others."[4]

**The Problem**

In its analysis of impacts, HCFA concluded that,

> "…the benefits of complying with the Patients' Rights CoP will far outweigh the costs involved [; and]…with regard to the restraint and seclusion standards for both acute medical and surgical care and behavior management, there should be no significant additional burden for, at least, the 80 percent of Medicare-participating hospitals accredited by JCAHO since the requirements are modeled on JCAHO's standards for both their hospital accreditation program and their behavior health care accreditation program. For the other 20 percent of hospitals that are non-accredited, there may be some one-time costs associated with developing policies and procedures for restraint and seclusion use. However, we believe that the benefits far outweigh the costs, because, from a risk management viewpoint, clear policies will protect the hospital from situations of inappropriate restraint and seclusion use and situations that may lead to patient injuries and death."[5]

[4] 62 Fed. Reg. at

[5] 64 Fed. Reg. at 36,086.

The problem not reflected in HCFA's analysis is that there are obvious and foreseeable circumstances in rural or frontier areas where it may be impossible to comply, in particular, with the one-hour standard due to the limited resources and staffs of these small hospitals. Rural physicians may be extreme distances away from the facility when circumstances dictate that a patient be restrained. It is not a mere difficulty or an inconvenience to meet the proposed standard in these types of cases, it is an impossibility.

Another problem is that interested commenters (i.e., rural providers) did not have an opportunity to express their views on the impact of the prescriptive requirements contained in the interim final rule before the rule went into effect (30 days after the interim rule was published). HCFA planned to complete its revision of the hospital CoPs at a later time, however, HCFA accelerated publication of the patients' rights CoP because of "recent reports [on death and injuries that] evidenced a pressing need for the codification and enforcement of these fundamental rights."[6] In its zeal to publish a good-intentioned regulation to protect patients' rights, some rather serious economic effects were overlooked. Some of the effects of the rule could have been alleviated—while maintaining patients' rights—through a more careful regulatory flexibility analysis.

**RFA Requirements**

Although the analytical requirements of the RFA do not generally apply to direct interim final rules, it is the opinion of this office that the RFA does apply in this case because there was a notice of proposed rulemaking (NPRM).[7] The interim final proposed by HCFA was certainly an outgrowth of the proposed rule; therefore, labeling it an interim final rule is not sufficient to bypass the requirements of the RFA. As a consequence, HCFA had a statutory duty to assess the impact of its regulation on small rural hospitals and consider less burdensome regulatory alternatives. Failure to do so puts HCFA in violation of the RFA in the opinion of this office.

With regard to the restraint and seclusion provisions, HCFA concluded that the impact of the regulation would be minimal because 80% of hospitals currently abide by JCAHO standards, and the 20% of non-accredited hospitals will only have a one time cost for developing policies and procedures. HCFA also concluded that the benefits would outweigh the costs because clear policies will protect the hospital from lawsuits.

There is no analysis of the impact on rural facilities that are unable to meet the 1-hour standard—some of which may fall into the 20% non-accredited category. As for its analysis of less burdensome alternatives, HCFA considered the ½-hour standard that exists in Pennsylvania, but rejected it because the agency realized that the requirement would not be realistic for rural areas. The requirement is to analyze less burdensome and

[6] Id. at 36,070.

[7] Section 604(a) of the RFA states, "when an agency promulgates a final rule under section 553 of this title [i.e., the Administrative Procedure Act], after being required by that section or any other law to publish a general notice of proposed rulemaking, …the agency shall prepare a final regulatory flexibility analysis."

not more burdensome requirements. Furthermore, no other alternatives were considered such as extending the time for rural hospitals, or allowing a physician to designate other staff to verify the clinical necessity for restraints or seclusion, or utilizing video monitoring via the Internet. Failure to consider the limited resources of rural hospitals and to devise alternatives also would jeopardize the very patients that HCFA is trying to protect.

During its consideration of alternatives, it may have been helpful for HCFA to consult with rural health industry representatives on this matter before adopting the 1-hour standard—particularly since the affected industry did not have a meaningful opportunity to comment prior to the effective date of the regulation. It is never advisable for agencies to make policy or regulatory decisions in a vacuum. Equally important, it is not advisable to adopt one-size-fits-all standards for different-sized businesses.

The Office of Advocacy believes that to the extent that HCFA did not consider the impact of its regulation on small rural hospitals or less burdensome alternatives, the agency did not comply with the RFA. The Office of Advocacy did not comment on these provisions when the rule was proposed in 1997 because the general and non-prescriptive nature of the original proposal would not have affected rural hospitals to the degree of the 1999 interim final rule. Our office did not comment on the 1999 rule because once the rule has essentially been finalized, the RFA is generally not the most effective tool for forcing change (--unless the Chief Counsel uses his amicus curiae authority pursuant to the filing of a complaint for judicial review by a small business, or unless there is an avenue for a section 610 review).

Section 610 of the RFA requires periodic review of regulations. Specifically, section 610 requires agencies to publish in the *Federal Register* a plan for periodic review of the rules issued by the agency which have or will have a significant economic impact on a substantial number of small entities. The purpose of the review is for agencies to determine whether such rules should continue without change, or should be amended or rescinded to minimize the impact on small entities. The rule generally applies to rules that have been on the books for ten years. Note, however, that 10 years is a maximum timeframe, and that there is no minimum amount of time for periodic review. In the case of the instant rulemaking, since the agency is aware that the 1-hour rule is causing problems, it is the opinion of this office that they have a duty to review the requirement and invite public comment pursuant to section 610.

Another course of action may be to petition HCFA, pursuant to section 553(e) of the Administrative Procedure Act (APA),[8] to change its rule based on the fact that the agency failed to comply with the RFA and because the regulation could result in unintended negative consequences for both rural services and patient safety. The Office of Advocacy is also willing to meet with HCFA officials to try and resolve this issue expeditiously without formally introducing the 553(e) petition. Please advise whether any or all of these options would best supplement your legislative efforts.

[8] This section of the APA gives all interested persons the right to petition for the issuance, amendment or repeal of a rule.

**Conclusion**

The Office of Advocacy appreciates the opportunity to present its views on this important matter. Please do not hesitate to contact our office if you have any questions, 202-205-6545 or 6533.

Sincerely,

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